

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK  
DAVID N. SHEINFELD,

Plaintiff,

-against-

B. BRAUN MEDICAL, et al.,

Defendants.

ANALISA TORRES, District Judge:

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23 Civ. 1622 (AT) (OTW)

**ORDER**

Plaintiff *pro se*, David N. Sheinfeld, brings this products liability action for failure to warn, design defects, and manufacturing defects in connection with an artificial disc replacement medical device (the “activL Device”) for patients with degenerative disc disease. Compl., ECF No. 1. Defendants moved to dismiss the complaint for failure to state a claim and lack of personal jurisdiction under Federal Rules of Civil Procedure 12(b)(6) and (b)(2). ECF No. 9. On April 14, 2023, the Court referred the motion to the Honorable Ona T. Wang for a report and recommendation. ECF No. 11.

Before the Court is Judge Wang’s Report and Recommendation (the “R&R”), dated February 1, 2024, which recommends that Defendants’ motion to dismiss be granted pursuant to Rule 12(b)(6) for failure to state a claim, and that Sheinfeld be given an opportunity to move to amend his complaint to replead his manufacturing defect claim. R&R at 11, ECF No. 32. Sheinfeld filed timely objections to the R&R. Pl. Obj., ECF No. 35; *see also* Def. Reply, ECF No. 38.

For the reasons stated below, the Court OVERRULES Sheinfeld’s objections and ADOPTS the R&R in its entirety.

## DISCUSSION<sup>1</sup>

### I. Standard of Review

A district court “may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge.” 28 U.S.C. § 636(b)(1)(C). When a party makes specific objections, the court reviews *de novo* those portions of the R&R to which objection is made. *Id.*; Fed. R. Civ. P. 72(b)(3). However, “when a party makes only conclusory or general objections, or simply reiterates [their] original arguments,” the court reviews the R&R strictly for clear error. *Wallace v. Superintendent of Clinton Corr. Facility*, No. 13 Civ. 3989, 2014 WL 2854631, at \*1 (S.D.N.Y. June 20, 2014) (citation omitted); *see also Bailey v. U.S. Citizenship & Immigr. Servs.*, No. 13 Civ. 1064, 2014 WL 2855041, at \*1 (S.D.N.Y. June 20, 2014) (“[O]bjections that are not clearly aimed at particular findings . . . do not trigger *de novo* review.”). Moreover, “a district judge will not consider new arguments raised in objections to a magistrate judge’s report and recommendation that could have been raised before the magistrate but were not.” *United States v. Gladden*, 394 F. Supp. 3d 465, 480 (S.D.N.Y. 2019) (citation omitted).

The Court may adopt those portions of the R&R to which no objection is made “as long as no clear error is apparent from the face of the record.” *Oquendo v. Colvin*, No. 12 Civ. 4527, 2014 WL 4160222, at \*2 (S.D.N.Y. Aug. 19, 2014) (citation omitted). A finding is clearly erroneous if the reviewing court is “left with the definite and firm conviction that a mistake has been committed.” *Easley v. Cromartie*, 532 U.S. 234, 242 (2001) (citation omitted).

“*Pro se* parties are generally accorded leniency when making objections.” *Pinkney v. Progressive Home Health Servs.*, No. 06 Civ. 5023, 2008 WL 2811816, at \*1 (S.D.N.Y. July 21,

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<sup>1</sup> The Court presumes familiarity with the facts and procedural history as detailed in the R&R, *see R&R* at 1–5, and does not summarize them here.

2008) (citation omitted). “Nonetheless, even a *pro se* party’s objections to a [r]eport and [r]ecommendation must be specific and clearly aimed at particular findings in the magistrate’s proposal, such that no party be allowed a ‘second bite at the apple’ by simply relitigating a prior argument.” *Id.* (citation omitted).

## II. Sheinfeld’s Objections

Sheinfeld objects to Judge Wang’s recommendation that the Court dismiss his failure-to-warn claim. First, he argues that without further discovery of Food and Drug Administration (“FDA”) trial data, he is unable to “plead sufficient facts to show that the [activL Device’s] warning was the proximate cause of his injuries.” R&R at 10–11 & n.5; *see* Pl. Obj. at 1–2. “A plaintiff who has failed adequately to state a claim is not entitled to discovery . . . , cabined or otherwise.” *Main St. Legal Servs., Inc. v. Nat'l Sec. Council*, 811 F.3d 542, 567 (2d Cir. 2016) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 686 (2009)). The Court agrees with the R&R that Sheinfeld has not stated a claim for failure to warn, and that amendment would be futile for the reasons stated in footnote five of the R&R. Accordingly, Sheinfeld is not entitled to receive additional FDA discovery that he only speculates could contain “potentially relevant evidence.” Pl. Obj. at 1.

Second, Sheinfeld attaches “new evidence” in the form of “FDA [t]rial data from other artificial disc manufacturers showing that disc migration is acceptable if it is <3.5mm.” Pl. Obj. at 2 & Exs. 1–3.<sup>2</sup> The additional studies, however, do not remedy the principal issue that Judge Wang identified: they “do[] not address whether this data had to be included in the activL Device warning materials.” R&R at 10. Sheinfeld argues that the studies illuminate an “actual known danger”—“[t]he possibility of unnecessary surgical intervention.” Pl. Obj. at 4. But, the

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<sup>2</sup> Sheinfeld included similar evidence with his opposition to Defendants’ motion to dismiss. R&R at 9 (citing ECF No. 16 at 10, Ex. 6).

evidence does not support the inference that surgery is necessarily inappropriate when the activL Device has migrated less than 3.5mm, or that Defendants were required to warn against surgical intervention in that case. *See* R&R at 10; *see also* ECF No. 16 at 9 (conceding that “there is some discretion left to doctors as to when intervention is appropriate”).

Sheinfeld’s objections are otherwise general, conclusory, or restate his original arguments. *Wallace*, 2014 WL 2854631, at \*1; *Pinkney*, 2008 WL 2811816, at \*1. The Court has reviewed the remainder of the thorough and well-reasoned R&R for clear error and finds none.

## CONCLUSION

For the foregoing reasons, the Court OVERRULES Sheinfeld’s objections to the R&R and ADOPTS the R&R in full. By **April 16, 2024**, Sheinfeld may request leave to amend his complaint to allege facts that (1) “the specific activL Device implanted in his spine was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction”; and (2) “the defect was the cause of his injury.” R&R at 11–12. The Clerk of Court is directed to terminate the motion at ECF No. 9 and mail a copy of the R&R and this order to Sheinfeld.

SO ORDERED.

Dated: March 12, 2024  
New York, New York



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ANALISA TORRES  
United States District Judge